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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,406	02/19/2002	Bettina Moeckel	219774US0X CIP	2133

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EXAMINER
HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/076,406	MOECKEL ET AL.	
	Examin r	Art Unit	
	Richard G Hutson	1652	

-- The MAILING DATE of this c mmunication appears n the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/3/2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-87* is/are pending in the application.

4a) Of the above claim(s) *11-17,20-23,26-29,32-35,42-82 and 85-87* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,18,19,24,25,30,31,36-41,83 and 84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/887,052* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-87 are at issue and are present for examination.

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-10, 18, 19, 24, 25, 30, 31, 36-41, 83 and 84, in Paper No. 7 is acknowledged. Applicants traversal with respect to the characterization of the inventions of Groups I-VIII as being unrelated because they each comprise a chemically unrelated structure capable of separate manufacture, use and effect, is on the ground(s) that the office has not provided reasons to assert this assertion. Applicants arguments are not found persuasive because as was previously stated the polynucleotides of Groups I, V, and VI are comprised of different nucleic acid sequences and the proteins of Groups II-IV are comprised of different amino acid sequences while the *Corynebacterium glutamicum* strains of Groups VII and VIII are living cells comprising polynucleotides, proteins, carbohydrates and lipids.

Applicants traversal with respect to the characterization of the inventions of Groups II-VIII and the inventions of Groups IX, XII, XV and XVI as being unrelated because the products of Groups II-VIII are neither used nor made by the methods of Groups IX, XII, XV and XVI, is on the ground(s) that the office has not provided reasons for this assertion. Applicants arguments are not found persuasive because as was previously stated the products of Groups II-VIII are neither used nor made by the methods of Groups IX, XII, XV and XVI, and thus it logically follows that the searches

necessary for one of the products groups would be unnecessary for the methods groups and thus the combination of the groups would cause an undue burden on the examiner in order to search and examine the groups together. As was previously stated, because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

As above applicants traversal with respect to the characterization of the inventions of Groups I-IV and VI-VIII and the inventions of Groups X and XIII as being unrelated because the products of Groups I-IV and VI-VII are neither used nor made by the methods of Groups X and XIII, is on the ground(s) that the office has not provided reasons for this assertion. Applicants arguments are not found persuasive because as was previously stated the products of Groups I-IV and VI-VIII I are neither used nor made by the methods of Groups X and XIII, and thus it logically follows that the searches necessary for one of the products groups would be unnecessary for the methods groups and thus the combination of the groups would cause an undue burden on the examiner in order to search and examine the groups together. As was previously stated, because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

As above applicants traversal with respect to the characterization of the inventions of Groups I-V and VI-VIII and the inventions of Groups X and XIII as being unrelated because the products of Groups I-IV and VI-VII are neither used nor made by the methods of Groups X and XIII, is on the ground(s) that the office has not provided reasons for this assertion. Applicants arguments are not found persuasive because as was previously stated the products of Groups I-IV and VI-VIII I are neither used nor made by the methods of Groups X and XIII, and thus it logically follows that the searches necessary for one of the products groups would be unnecessary for the methods groups and thus the combination of the groups would cause an undue burden on the examiner in order to search and examine the groups together. As was previously stated, because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

As above applicants traversal with respect to the characterization of the inventions of Groups I-V and VII-VIII and the inventions of Groups XI and XIV as being unrelated because the products of Groups I-V and VII-VIII are neither used nor made by the methods of Groups XI and XIV, is on the ground(s) that the office has not provided reasons for this assertion. Applicants arguments are not found persuasive because as was previously stated the products of Groups I-IV and VI-VIII I are neither used nor made by the methods of Groups X and XIII, and thus it logically follows that the searches necessary for one of the products groups would be unnecessary for the

methods groups and thus the combination of the groups would cause an undue burden on the examiner in order to search and examine the groups together. As was previously stated, because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicants traversal with respect to the characterization of the inventions of Groups IX-XVII as independent as these different groups comprise "different steps" is on the ground(s) that the office has not provided reasons for this assertion. Applicants arguments are not found persuasive because as was previously stated the different Groups IX-XVII are drawn to different methods or processes which comprise different steps and are thus drawn to patentably distinct inventions. As was previously stated, because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicants traversal with respect to the characterization of the inventions of Groups I and Groups IX, XII, XV, and XVI as product and process of use and the product as claimed can be used in a materially different process of using that product such as one in which the are used to synthesize mutant polynucleotides, is on the ground(s) that the office has not provided reasons for this assertion. Applicants arguments are not found persuasive because as was previously stated, because these

inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper. Applicants comments regarding the proposed use of the claimed composition as a detergent additive being materially different from the claimed use are acknowledged however somewhat confusing in the context of this traversal.

As above applicants traversal with respect to the characterization of the inventions of Groups V and Groups X and XIII as product and process of use and the product as claimed can be used in a materially different process of using that product such as one in which the are used to synthesize mutant polynucleotides, is on the ground(s) that the office has not provided reasons for this assertion. Applicants arguments are not found persuasive because as was previously stated, because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper. Applicants comments regarding the proposed use of the claimed composition as a detergent additive being materially different from the claimed use are acknowledged however somewhat confusing in the context of this traversal.

As above, applicants traversal with respect to the characterization of the inventions of Groups VI and Groups XI and XIV as product and process of use and the

product as claimed can be used in a materially different process of using that product such as one in which the are used to synthesize mutant polynucleotides, is on the ground(s) that the office has not provided reasons for this assertion. Applicants arguments are not found persuasive because as was previously stated, because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper. Applicants comments regarding the proposed use of the claimed composition as a detergent additive being materially different from the claimed use are acknowledged however somewhat confusing in the context of this traversal.

Finally applicants traverse the restriction requirement on the additional grounds that a search of all of the claims would not impose a serious burden on the Office. However, applicants have not provided reasons and/or examples to support this conclusion. This argument is not found persuasive for the following: While the searches for many of the groups overlap, they are not coextensive. For example, search of Group II would require a search of subclass 530/350, a search of Group IX would require search of subclass 435/106, a search of Group XII would require search of subclass 435/6. A search of each of these subclasses would be unnecessary the search of the elected group I. Further Groups I, V and VI are each drawn to structurally different **polynucleotides**, that are not capable of use together as previously stated and are thus distinct and restrictable for the reasons stated.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-17, 20-23, 26-29, 32-35, 42-82 and 85-87 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 7.

Priority

Applicants claim of priority to German Application No. DE10107229.5, filed February 16, 2001, is acknowledged. It is further noted that a certified copy of this priority document is present in the application file. It is further noted that this application is a continuation –in part of 09/887,052, filed 6/25/2001.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

Applicants filing of information disclosures, Paper No. 5, filed 12/6/2002, is acknowledged., however many of the references are missing. Those present and considered have been initialed.

Claim Objections

Claims 37 and 39 are objected to because of the following informalities:

Claims 37 and 39 each recite specific stains of *Corynebacterium,* and *Brevibacterium* (i.e. FERM 1079, FERM-P 1708, FERM-P1712, FERM-P6463, FERM-P6464, DM58-1, DG 52-5, DSM 5714 and DSM-12866.). In some recitations, such as FERM-P 1708, applicants include a "space" between "P" and "1708", where as in others, such as FERM-P1712, applicants do not. This is not consistent with the specification on page 9, lines 26-34. It is suggested that applicants maintain consistency throughout the specification including the claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 9, 40 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 9 are each indefinite in that they recite "...a protein having the activity of the β-subunit of RNA polymerase B." It is unclear what "activity of the β-subunit of RNA polymerase" applicants refer. A biologically active protein may encompass a variety of different biological activities. These include but are not limited to immunological activity, such as acting as an antigen for an antibody; regulatory

activity, such as that exhibited by many proteins which control transcription and/or translation of not only their encoding nucleic acids but other nucleic acids as well; or enzymatic activity, for example, RNA polymerase activity. It is not clear what is encompassed by the "activity" of β-subunit of RNA polymerase B and if includes biological activities in addition to enzymatic activity.

Claim 40 (41 dependent on) is indefinite in that it is unclear in that it is drawn to "A *Coryneform* bacterium which comprises an enhanced rpoB gene." Specifically it is unclear in what an "enhanced rpoB gene" is and what it encompasses.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 5-9 are directed to all possible polynucleotides which are at least 70%, 80% or 90% identical to the polynucleotide of claim 3, (SEQ ID NO: 1) (claims 5-8) and all possible polynucleotides which hybridize under stringent conditions of 5X SSC at a temperature from 50 to 68°C. Claim 10 is directed to all possible polynucleotides which comprises at least 15 consecutive nucleotides of the polynucleotide of claim 3 (SEQ ID NO: 1). The specification, however, only provides a single representative species of

polynucleotide (i.e. SEQ ID NO: 3) encompassed by these claims. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these enzymes by any identifying structural characteristics or properties. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 5-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide which encodes a protein having the amino acid sequence of SEQ ID NO: 2, does not reasonably provide enablement for any polynucleotide which comprises a mere 15 consecutive nucleotides of SEQ ID NO: 3 or is 70-90% identical to SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of

direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1-5 are so broad as to encompass any polynucleotides which is at least 70%, 80% or 90% identical to the polynucleotide of claim 3, (SEQ ID NO: 1) (claims 5-8) and any polynucleotide which hybridizes under stringent conditions of 5X SSC at a temperature from 50 to 68°C. Claim 10 is so broad as to encompass any polynucleotides which comprises at least 15 consecutive nucleotides of the polynucleotide of claim 3 (SEQ ID NO: 1). The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claims. The claims rejected under this section of U.S.C. 112, first paragraph, place insufficient structural and no functional limits on the claimed polynucleotides. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. The same is true of a polynucleotide sequence, as the nucleic acid sequence of the polynucleotide directly correlates with the amino acid sequence of the polypeptide. However, in this case the disclosure is

limited to a polynucleotide which encodes a protein having the amino acid sequence of SEQ ID NO: 2.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a polynucleotides sequence where nucleic acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any polynucleotide and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given polynucleotide to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass those polynucleotides having the claimed structural relationship to SEQ ID NO: 1, because the specification does not establish: (A) regions of the polynucleotide structure which may be modified without effecting the desired activity; (B) the general tolerance of the claimed polynucleotides to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any nucleic acid residue of SEQ ID NO: 1 with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the desired activity claimed and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity)

are not well understood and are not predictable (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), it would require undue experimentation for one skilled in the art to arrive at the majority of those polynucleotides of the claimed genus.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any polynucleotide with the claimed structural relationship to SEQ ID NO: 1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 37 and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention of claims 37 and 39 appears to employ novel strains of *Corynebacterium,* and *Brevibacterium*(i.e. FERM 1079, FERM-P 1708, FERM-P1712, FERM-P6463, FERM-P6464, DM58-1, DG 52-5, DSM 5714 and DSM-12866.) Since

these strains are essential to the claimed host cells, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. These organisms are not fully disclosed, nor have they been shown to be publicly known and freely available. The enablement requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the specific strains of *Corynebacterium,* and *Brevibacterium*.. Accordingly, it is deemed that a deposit of these stains should have been made in accordance with 37 CFR 1.801-1.809.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 8 and 10 are rejected under 35 U.S.C. 102(a) as being anticipated by Imboden et al. (Database EMBL on line, Accession No. U12205.1, March 2000).

Imboden et al. teach the rpoB gene of *Mycobacterium tuberculosis* which comprises a polynucleotide that has a best local similarity score of at least 71% and comprises many regions of at least 15 consecutive nucleotides of SEQ ID NO: 1. Thus claims 5, 8 and 10 are anticipated by Imboden et al.

Claims 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Honore et al. (Database EMBL on line, Accession No. Z14314, Feb 1993, See IDS ref AR).

Honore et al. teach the rpoB gene of *Mycobacterium leprae* which comprises a polynucleotide that has comprises many regions of at least 15 consecutive nucleotides of SEQ ID NO: 1. Thus claim 10 is anticipated by Honore et al.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 2, 3, 4, 9, 18, 19, 24, 25, 30, 31, 36, 38, 83, and 84 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 2, 3, 4, 9, 18, 19, 24, 25, 36, 38, 83, and 84 of copending Application No. 09/887,052. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5, 6, 7, 8, 10, 37, 39, 40 and 41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6, 7, 8, 36, 38, 40 and 41, of copending Application No. 09/887,052. An obvious type double patenting rejection is appropriate where conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g.., *In re* Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re* Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re* Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 6, 7, 8, 36, 38, 40 and 41, of copending Application No. 09/887,052 are drawn to an isolated polynucleotide which is at least 86% identical to a polynucleotide which encodes a β-subunit of RNA polymerase B having the amino acid

sequence of SEQ ID NO: 2, and specific host cells comprising said polynucleotides and host cells in which the polynucleotide is enhanced. Thus claims 6, 7, 8, 36, 38, 40 and 41 anticipate claims 5, 6, 7, 8, 10, 37, 39, 40 and 41 of the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
May 15, 2003